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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/799,192	03/12/2004	Imad Ed. Tarabishy	V-3301-022	8181
7590	01/27/2005			EXAMINER
William S. Van Royen David W. Pettis, Jr., P.A. Suite 700 501 E Kennedy Blvd Tampa, FL 33602-5200			BLANCO, JAVIER G	
			ART UNIT	PAPER NUMBER
			3738	
DATE MAILED: 01/27/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/799,192	TARABISHY, IMAD ED.
	Examiner	Art Unit
	Javier G. Blanco	3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 05 November 2004.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) 7 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1,5,6,10 and 11 is/are rejected.
- 7) Claim(s) 2-4,8,9 and 12 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 12 March 2004 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election of hip joint prosthesis: species C (Figure 15) in the reply filed on November 5, 2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. Claim 7 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on November 5, 2004.

### ***Specification***

3. The disclosure is objected to because of the following informalities:
  - a. Please update the CROSS-REFERENCE TO RELATED APPLICATIONS section (i.e., now US 6,755,865). Appropriate correction is required.
  - b. The BRIEF DESCRIPTION OF THE DRAWINGS section does not have a brief description of Figures 35-57. Appropriate correction is required.

### ***Drawings***

4. The drawings are objected to because reference legend 38B have been used to designate two different figures. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the

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sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### *Claim Objections*

5. Claims 1, 8, and 10 are objected to because of the following informalities:

a. Regarding claim 1, please add --segmented-- in front of "shell" (see line 3 and line 5).

Appropriate correction is required.

b. Regarding claim 8, please add --longitudinal-- in front of "ends" (see line 6). Appropriate correction is required.

c. a. Regarding claim 10, please (i) add --and-- in front of "a neck" (see line 2) and in front of "a body" (see line 2), and (ii) add --open end-- after "second" (see line 5). Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-6 and 8-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- a. Regarding claim 1, "the hip bone of a patient" (see line 3) lacks antecedent basis. Claims 2-6 and 8-12 depend on claim 1.

***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 1, 5, and 6 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by DeCarlo, Jr. (US 4,524,467).

Referring to Figures 1, 2, and 10, DeCarlo, Jr. discloses a joint prosthesis comprising: (i) at least one segmented shell (body portion 64); (ii) means (e.g., polar pin 50) for attaching said shell to a prepared area on a hip bone of a patient; (iii) a cup (socket bearing 12) *sized and*

*configured to* be received in said segmented shell, forming a new acetabular socket; (iv) a second shell (retaining ring portion 74) designed and *configured to* be received in said segmented shell and *sized and configured to* receive said cup therein; and (v) a shaft having a ball (ball 10), a neck (neck 16), and a body (stem 18).

10. Claims 1 and 5 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Hyde, Jr. (US 6,589,281 B2).

Referring to Figures 20-22, Hyde, Jr. discloses a joint prosthesis comprising: (i) at least one segmented shell (acetabular assembly 191) comprising implant modules 192 and a base (base 195); (ii) means for attaching said shell to a prepared area on a hip bone of a patient (see threads 196); (iii) a cup (cup 193) *sized and configured to* be received in said segmented shell, forming a new acetabular socket; and (iv) a shaft (prosthesis assembly 180) having a ball (head 183), a neck (neck 184), and a body (core implant module 182 and/or stem components 152).

#### ***Claim Rejections - 35 USC § 103***

11. Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hyde, Jr. (US 6,589,281 B2) in view of Grimes (WO 00/48535 A1).

Hyde, Jr. discloses the invention as claimed in claims 1 and 5. Although Hyde, Jr. discloses the desirability of preventing/removing wear debris and introducing therapeutic agents into the joint area, he/she did not particularly disclose the stem or shaft as having a set of channels with a structure (i.e., a first main channel having dual open ends, a second main channel having an open end and a closed end; secondary channels interconnecting with one of the main channels) as disclosed in claims 10 and 11.

However, that structure is known in the art. For example, Grimes discloses a joint prosthesis comprising a shaft having: (i) at least one tube (primary channel 616) having first and second open ends and extending from the bottom surface of said body and opening through said neck (see Figures 29 and 30); (ii) a second tube (primary channel 614) having an open end extending from the bottom surface of said body and a second closed end (see Figures 29 and 30); and secondary tubes (secondary channels 635-639) passing through a side wall of said body and through said second tube such that said secondary tubes are in fluid communication with said second tube in order to apply cement to the prosthesis-bone interface, remove wear debris, and/or introduce therapeutic agents into the joint area (see Figures 29 and 30; see page 46, lines 7-24; see entire document). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have combined the teachings of a joint prosthesis stem/shaft having at least one tube having first and second open ends, a second tube having an open end and a second closed end, and secondary tubes passing through a side wall of said body and through said second tube, as taught by Grimes, with the joint prosthesis shaft/stem of Hyde, Jr., in order to apply cement to the prosthesis-bone interface, remove wear debris, and/or introduce therapeutic agents into the joint area.

*Allowable Subject Matter*

12. Claims 2-4, 8, 9, and 12 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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***Conclusion***

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Noiles (US 4,662,891), Schryver (US 5,226,917), Maumy et al. (US 5,735,901), Marlow (US 5,989,294 A), Shah (US 6,010,535), and Harris (US 6,248,132).

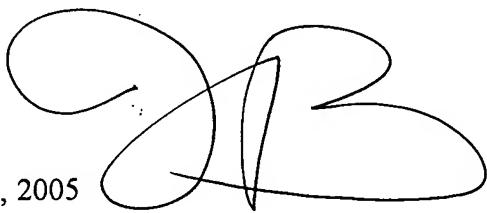
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 571-272-4747. The examiner can normally be reached on M-F (7:30 a.m.-4:00 p.m.), first Friday of the bi-week off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 703-308-2111. The fax phone numbers for the organization where this application or proceeding is assigned is 703-872-9306 for regular communications and After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

JGB

January 21, 2005



David H. Willse  
Primary Examiner